UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNTED STATES OF AMERICA et al.
ex rel. JULIE LONG,
Plaintiffs,

v. CIVIL ACTION NO. 16-12182-FDS

JANSSEN BIOTECH, INC.,
Defendant.

MEMORANDUM AND ORDER ON JANSSEN BIOTECH'S MOTION TO COMPEL COMPLETE ANSWERS TO INTERROGATORIES (#382)

KELLEY, U.S.M.J.

I. Introduction.

In this motion, Janssen asks this court to compel relator to answer four contention interrogatories. As explained below, the part of the motion concerning Interrogatory No. 6 is DENIED as moot, since relator has agreed to supplement her answer to it. (#390 at 7-8.) The remainder of the motion, concerning Interrogatories Nos. 13, 14, and 15, is DENIED.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free business advisory services to physicians who prescribed its medications, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a). Relator Julie Long alleges that Janssen Biotech, Inc., a company that manufactures and sells two infusible drugs, Remicade and Simponi ARIA, improperly employed teams of practice advisors, including relator,

and hired outside consultants to provide services such as presentations, advice, and customized analyses to doctors to assist them in running profitable infusion businesses, called in-office infusion suites ("IOIs"). The facts of the case and a detailed analysis of the claims in the Second Amended Complaint (#55) are set out in Chief Judge Saylor's Order and Memorandum on Defendant's Motion to Dismiss. (#75.) This court previously has issued discovery orders, *see, e.g.*, ##282, 322, 375, which recount the lengthy history of the discovery disputes in this case.

II. The Law.

When a party seeks a response to a contention interrogatory, "the court may order that the interrogatory need not be answered until designated discovery is complete, or until a pretrial conference or some other time." Fed. R. Civ. P. 33(a)(2). As the rule makes clear, the court has wide discretion to decide whether to delay a party's obligation to answer contention interrogatories based on the circumstances of the case. *Compare Britton v. Marcus, Errico, Emmer & Brooks, P.C.*, No. 18-cv-11288-IT, 2021 U.S. Dist. LEXIS 153225, at *6 (D. Mass. Aug. 13, 2021) (finding no basis to delay a party's responses to contention interrogatories where responses would be "based on the materials already in their possession"), *with HealthEdge Software, Inc. v. Sharp Health Plan*, No. 19-cv-11020-ADB, 2021 U.S. Dist. LEXIS 88061, at *13 (D. Mass. May 6, 2021) (delaying response where party had not yet reviewed its own documents or received documents from opposing party). For example, courts have allowed a motion to compel responses to contention interrogatories where "the original fact discovery deadline set by the [c]ourt" had passed. *In re New Eng. Compounding Pharmacy Prods. Liab. Litig.*, No. 13-md-2419-RWZ, 2015 U.S. Dist. LEXIS 195156, at *48 (D. Mass. Sep. 8, 2015).

III. Janssen's Motion to Compel.

Before discussing the present motion, the court describes a previous order that looms large in the parties' dispute here. In arguing that the court should grant this motion, Janssen heavily relies on a September 2022 Order in which this court required Janssen to respond to three contention interrogatories regarding three of its affirmative defenses. (#322.) The contention interrogatories that this court held Janssen must answer were: first, to state the facts supporting its contention that Janssen reasonably interpreted the statutes and regulations at issue; second, to state the specific analyses that Janssen performed and advice it received that it relied on in reaching its asserted belief that it was acting lawfully; and finally, to state the facts to support its contention that any false claims or false statements were not made knowingly. (#322 at 3-4.) Janssen objected to having to answer the contention interrogatories, in part on the grounds that they were premature and it should not be required to answer them until the close of fact discovery. (#307-2 at 8; #309 at 10-11.) In ruling against Janssen, this court noted that the timing of contention interrogatories varies according to the circumstances of each case, and that because "phase one discovery in this case [was] drawing to a close," and summary judgment motions would follow, Janssen should answer. (#322 at 10.) In addition, this court found that Janssen should answer because the "documentation supporting Janssen's responses to these interrogatories is necessarily in Janssen's possession where Janssen avers that it followed its own internal 'practices and standards' and 'approval process' in order to comply with applicable laws and regulations." *Id*. at 9.

Soon after the court ordered Janssen to answer the three contention interrogatories, Janssen made its own demand on relator that she respond to contention interrogatories. (#390 at 6.) After extensive negotiations, *see* #383 at 2-4, Janssen filed the present motion, moving to compel relator to answer contention Interrogatories Nos. 6, 13, 14, and 15. (#382 at 1.)

A. Interrogatory No. 6.

Interrogatory No. 6 asks relator to

> [i]dentify each instance in which You provided in-office infusion support services to any Phase One Account, including (i) the date on which You provided the in-office infusion support service(s); (ii) the Phase Once Account to which You provided the service(s); and (iii) the in-office infusion support service(s) provided. (#383 at 6.)

Relator originally objected to this interrogatory because the information it sought was in Janssen's possession and it would be unduly burdensome for her to cull the information from Janssen's records, which relator claims have not yet been produced. (#390 at 7.) She now states that she agrees to provide Janssen a supplemental response to this interrogatory, as Janssen recently clarified that it is "asking only for Plaintiff to identify what she knows, based upon her own records and recollection, the instances in which she provided IOI Support Services to the sample accounts from Relator's former territory." *Id*. Thus, the court denies this request as moot.

B. Interrogatories Nos. 13, 14, and 15.

Interrogatory No. 13 asks relator to "[s]tate the basis for Your contention that the claims identified in Your response to Interrogatory No. 12 were False Claims." (#383 at 11.) [1]

Interrogatory No. 14 asks relator to "[s]tate the basis for Your contention in Count I, as it relates to the Phase One Accounts, that Defendant 'caused the health care providers to present claims for reimbursement to Medicare . . . that were false or fraudulent because the providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.'" *Id*. at 13-14.

[1] Interrogatory No. 12 states: "Identify all False Claims that you allege Defendant caused the Phase One Accounts to submit to Medicare for the reimbursement of Remicade and Simponi ARIA." (#383 at 11 n.8.)

Interrogatory No. 15 asks relator to "[s]tate the basis for Your contention in Count II, as it relates to the Phase One Accounts, that 'Janssen caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare.'" *Id.* at 16.

Relator responded (in part) to Interrogatory No. 13:

> The claims identified in Plaintiff's response to Interrogatory 12 were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B) because: (a) The claims "include[d] items or services resulting from a violation of [the Anti-Kickback Statute] …" 42 U.S.C. § 1320a-7b(g). And "an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act]." *United States v. Regeneron Pharm. Inc*., Civ. No. 20-11217-FDS, 2020 WL 7130004, at *7 (D. Mass. Dec. 4, 2020) (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)). (b) In the claim, the health care providers falsely represented to Medicare that they had not received illegal remuneration and that they had complied with the Anti-Kickback Statute in providing and billing for the Remicade, Simponi ARIA, and related infusions. The express representation providers made in bills submitted on Form CMS-1500 to Medicare regarding compliance with the AntiKickback Statute can be viewed at ¶ 28 of the Second Amended Complaint and CMS000005 – CMS000008. (c) The health care providers had falsely certified in their provider enrollment agreements with Medicare that they would comply with the Anti-Kickback Statute. The express representation providers made in enrollment agreements with Medicare regarding compliance with the Anti-Kickback Statute is publicly available and can also be viewed at ¶ 26 of the Second Amended Complaint. In submitting claims for payment for Remicade, Simponi ARIA, and related infusion services after receiving the services and related presentations and programs identified in the response to Interrogatory 2, the providers falsely represented that they were complying with the certification made in their enrollment agreements. Plaintiff will supplement this response and list the evidentiary support for the falsity element of her False Claims Act violation claims after substantial discovery has been completed.

(#383 at 11-12.)

Relator responded (in part) to Interrogatory No. 14:

> As a result of its knowing and willful offering and provision of the services and related presentations and programs identified in Plaintiff's response to Interrogatory 2 to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries in violation of the Anti- Kickback Statute, Defendant caused the health care providers associated with the Phase 1 Accounts to present claims for reimbursement to Medicare that were false or fraudulent under 31 U.S.C. § 3729(a)(1)(A). The claims for reimbursement submitted by the health care

providers associated with the Phase 1 Accounts were false claims under the False Claims Act because they included items and services (Remicade, Simponi ARIA, and/or related infusion procedures) resulting from violations of the Anti-Kickback Statute. See 42 U.S.C. § 1320a-7b(g); *United States v. Regeneron Pharm. Inc*., Civ. No. 20-11217-FDS, 2020 WL 7130004, at *7 (D. Mass. Dec. 4, 2020) ("an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act].") (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were also false claims under the False Claims Act because the health care providers falsely certified, stated, and/or represented in connection with each claim that they submitted to Medicare on or after October 28, 2010, in which they requested and received reimbursement for Remicade, Simponi ARIA, and/or related infusion services, that the claim complied with the Anti-Kickback Statute. In addition, Plaintiff directs Janssen to Plaintiff's Second Amended Complaint and Plaintiff's briefing in opposition to Janssen's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures. Plaintiff will update her initial disclosures once Janssen has provided all the witness information that the Court ordered it to provide in the March 9, 2023 Memorandum and Order. Plaintiff will supplement this response and list the evidentiary support for her 31 U.S.C. § 3729(a)(1)(A) violation claims after substantial discovery has been completed.

(#383 at 14-15.)

Relator responded (in part) to Interrogatory No. 15:

As a result of its knowing and willful offering and provision of the services and related presentations and programs identified in Plaintiff's response to Interrogatory 2 to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries in violation of the Anti- Kickback Statute, Defendant caused the health care providers associated with the Phase 1 Accounts to present claims for reimbursement to Medicare that were false or fraudulent under 31 U.S.C. § 3729(a)(1)(A). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were false claims under the False Claims Act because they included items and services (Remicade, Simponi ARIA, and/or related infusion procedures) resulting from violations of the Anti-Kickback Statute. See 42 U.S.C. § 1320a-7b(g); *United States v. Regeneron Pharm. Inc*., Civ. No. 20-11217-FDS, 2020 WL 7130004, at *7 (D. Mass. Dec. 4, 2020) ("an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act].") (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were also false claims under the False Claims Act because the health care providers falsely certified, stated, and/or represented in connection with each claim that they submitted to Medicare on or after October 28, 2010, in which they requested and received reimbursement for Remicade, Simponi ARIA, and/or related infusion services, that the claim

> complied with the Anti-Kickback Statute. In addition, Plaintiff directs Janssen to Plaintiff's Second Amended Complaint and Plaintiff's briefing in opposition to Janssen's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures. Plaintiff will update her initial disclosures once Janssen has provided all the witness information that the Court ordered it to provide in the March 9, 2023 Memorandum and Order. Plaintiff will supplement this response and list the evidentiary support for her 31 U.S.C. § 3729(a)(1)(A) violation claims after substantial discovery has been completed.

(#383 at 16-17.)

Relator's answers are, obviously, very general. She objects to answering in any more detail because that would require her to "identify every document, communication, act or omission and additional fact regarding" her claims, a task that would be unduly burdensome at this stage of the litigation. (#390 at 8, 12-14.)[2] Further, relator is still awaiting substantial discovery from Janssen and "should not have to respond to Janssen's contention interrogatories before she received and has an opportunity to review the responsive materials produced by Janssen and can exhaustively identify all documents supporting her claims and contentions." *Id*. at 9. Because the questions are so broad, relator complains that she would be required to "tip her hand" "by giving Janssen a roadmap to her pretrial strategy." *Id*. at 11. Finally, answering would require relator to reveal attorney work product in the selection and compilation of documents in preparation for depositions. (#390 at 15.)

Janssen responds first, that because the court permitted relator to seek contention interrogatories from Janssen, Janssen ought to be permitted to do the same. (#383 at 5; #391 at 4.) Second, Janssen states that relator "only has to respond for herself based on her personal views and knowledge," *id*.; in other words, realtor's answers would not require her to lay out her entire

[2] Relator points out that as reported in the Medicare claims data that she produced to Janssen, the doctors associated with the eleven sample accounts from relator's territory submitted approximately 12,000 claims to Medicare for reimbursement between November 2010 and February 2016. (#390 at 12.)

case, at least to the extent it is based on information originally outside of her possession, knowledge, or control. In its reply, Janssen reiterates that the information sought is "most notably, in [relator's] own mind." (#391 at 2.) However, later in that document Janssen asks the court to "order Relator to answer the interrogatories based on her personal knowledge *and the records currently available to her*." *Id*. at 3 (emphasis added). Thus the court understands that in fact, Janssen is not simply asking realtor to convey her own ideas, as they exist "in her own mind," about the questions asked, but also to cite support from the more than 3,000,000 pages relator has received in discovery thus far.

Relator has the better of the argument. First, it is not the case that because the court has ordered one party to answer contention interrogatories, it is open season on contention interrogatories for both parties. The interrogatories that Janssen was asked to answer concerned only three of its thirty-eight affirmative defenses, all of which were asserted, as defenses often are, without support or explanation, *see* #83 at 51-55. The information sought was in Janssen's sole possession –Janssen did not have to receive discovery from relator and review it before being able to answer. Finally, the three contention interrogatories relator served on Janssen concerned a long-contested issue in this case that has been difficult to address in discovery, namely, Janssen's understanding regarding the lawfulness of the IOI support services. Relator has repeatedly demanded information from Janssen concerning its good faith belief defense and related defenses and has received limited discovery in response. Janssen has made clear that it is not relying on an advice of counsel defense. (#264-8.) Chief Judge Saylor previously weighed in on the subject, finding that Janssen's "assertion that it acted in good faith by adhering to internal-compliance protocols, which included a legal review, does not necessarily implicate privileged communication to such a degree" that Janssen had waived privilege over requested documents. (#303 at 4.) This

court reluctantly circumscribed the discovery that Janssen must produce from legal counsel in an effort to put reasonable limits on discovery at this phase of the case. *See* #375 at 11-14 (discussing the progression of requests from relator and denying relator's request for information about the reviews and advice Janssen received about the legality of the services in question). In sum, the contention interrogatories that this court ordered Janssen to answer were narrowly tailored to address a critical issue in this case that Janssen had thus far largely avoided addressing and over which it controlled all relevant information. *See In re Facebook, Inc*., No. MDL 12-2389, 2016 WL 5080152, *3 (S.D.N.Y. July 7, 2016) (holding that contention interrogatories are appropriately reserved for after discovery, except "in the rare event that future discovery would be unhelpful or unlikely to elicit issues and establish a necessary factual foundation in that particular litigation."). That is not the case with the interrogatories posed by Janssen to relator, which essentially ask relator to lay out her entire case against Janssen while discovery remains ongoing and impose upon her unnecessarily arduous obligations to update as new information becomes available to her.[3]

IV. Conclusion.

For the above reasons, Janssen's motion to compel regarding Interrogatory No. 6 is DENIED as moot, and the remainder of the motion is DENIED.

June 1, 2023

/s/ M. Page Kelley
M. Page Kelley
Chief United States Magistrate Judge

[3] The court need not consider relator's attorney work product argument at this time. *See* #390 at 12.